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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/458,610

12/10/1999

ELIZABETH G. NABEL

8642/88

9076

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07/17/2006

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,610

Applicant(s)

NABEL ET AL.

Examiner

Anne Marie S. Wehbe

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1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106-109, 120, 125-131, 134, 135 and 142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 109, 121-131, 134, 135 and 142 is/are allowed.
- 6) ☒ Claim(s) 106-108 and 120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's after-final amendment and response received on 5/25/06 has been entered. Claims 1-105, 110-119, 121-124, 132-133, 136-141, and 143-146 are canceled. Claims 106-109, 120, 125-131, 134-135, and 142 are pending in the instant application.

In view of new grounds of rejection applied below, the finality of the previous office action is withdrawn and prosecution resumes in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office actions.

Claim Rejections - 35 USC 112

The rejection of claims 109-112, 114-119, 121-135, and 138-142 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of the cancellation of claims 110-112, 114-119, 121-124, 132-133 and 136-141 and further in view of the amendment of the remaining claims to the treatment of vascular injury in a mammal comprising the delivery to a blood vessel at the site of injury a transformed syngeneic or autologous vascular smooth muscle or endothelial cell comprising an exogenous nucleic acid encoding basic fibroblast growth factor. Claims 109, 125-131, 134-135 and 142 now correspond in scope to the identified scope of enablement set forth in previous office actions.

Double Patenting

The rejection of pending claims 106-109, 114-118, 121-131, and 142-146 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-14 of U.S. Patent No. 6,203,991 (3/20/01), the '991 patent, is withdrawn in view of the cancellation of claims 114-118, 121-124 and 143-146 and the applicant's submission of a proper terminal disclaimer over U.S. Patent No. 6,203,991 on 5/25/06.

The following new rejections/objections apply.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 106-108 and 120 are newly rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,001,350 (1999), hereafter referred to as Mulligan-2, or U.S. Patent No. 5,674,722 (1997), hereafter referred to as Mulligan-1. Mulligan-2 is a direct continuation of Mulligan-1 and as such, the specifications of both patents is the same. Column references below refer to the Mulligan-1 specification.

The applicant claims a method of introducing a protein in a mammal comprising delivering to a blood vessel in the mammal a transformed vascular cell, wherein the vascular cell originates from or is syngeneic to the mammal and comprises an exogenous nucleic acid encoding a protein, wherein the protein is expressed when implanted into the mammal. The applicant further claims said method wherein the cells are vascular endothelial or smooth muscle cells, where the cells attach to the wall of the blood vessel in the mammal, or wherein the nucleic acid encodes a marker protein.

Mulligan teaches methods of delivery and expressing a protein in a mammal by removing vascular endothelial cells from the mammal, transducing the cells *in vitro* with a retrovirus encoding a protein of interest, and delivering the transduced cells to a blood vessel in the same mammal from the cells were derived using a catheter (Mulligan, columns 7 and 19-22). Mulligan further teaches the gene of interest is a marker gene (Mulligan, column 7). Further, Mulligan demonstrates expression of the marker gene from the transplanted transduced endothelial cells *in vivo* (Mulligan, Table II). Mulligan further teaches that implanted vascular endothelial cells

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attach to the blood vessel wall (Mulligan, column 7). Thus, by teaching all the limitations of the claims as written, Mulligan anticipates the instant invention as claimed.

Claims 109, 125-131, 134-135 and 142 are free of the prior art of record, including the Mulligan patents cited above. The Mulligan patents do not disclose a nucleic acid encoding basic fibroblast growth factor or suggest treating a vascular injury by expressing basic fibroblast growth factor from transduced vascular endothelial cells implanted into a blood vessel in the mammal.

Claims 109, 125-131, 134-135 and 142 are allowable over the prior art of record.

Specification

The disclosure is objected to because of the following informalities: the first page, first paragraph, of the specification, sets forth applicant's claim for benefit of priority. The paragraph was added in the preliminary amendment filed on 12/10/99. It states that this application is a continuation of U.S. Serial No. 08/889,399, which is a continuation of U.S. Serial No. 08/376,521. However, U.S. Serial No. 08/376,521 is an unrelated application by different inventors to unrelated subject matter. It is believed that the applicant meant to refer to U.S. Serial No. 08/376,522.

Appropriate correction is required.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

